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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,301	03/18/2002	Kenji Miyanishi	Q69010	1176

23373 7590 06/12/2003

SUGHRUE MION, PLLC  
2100 PENNSYLVANIA AVENUE, N.W.  
WASHINGTON, DC 20037

EXAMINER
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BENNETT, RACHEL M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 06/12/2003

5

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/088,301

Applicant(s)

MIYANISHI ET AL.

Examiner

Rachel M. Bennett

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 March 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> . | 6) <input type="checkbox"/> Other:  |

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### **DETAILED ACTION**

The examiner acknowledges receipt of IDS filed 3/18/02 and Preliminary Amendment A filed 3/18/02.

#### ***Specification***

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "functional food" is not clearly defined in the claims or instant specification. Clarification is requested.

#### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by SAPPORO BREWERS LTD (WO/99/33939 A1).

Applicants claim a method of producing a sphingoglycolipid-containing product, which comprises the steps of adding an organic solvent to a tuberous and corm vegetable or oil cake and extracting a sphingoglycolipid. Applicants disclose it is known in the art that ceramides composed of sphingosine and fatty acids.

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SAPPORO BREWERS LTD disclose a process for efficiently and conveniently obtaining barley malt oil which is rich in vegetable ceramide-associated substances having a high safety and originating in plants with a favorable image as a material; and barley malt oil obtained by this process which is rich in the vegetable ceramide-associated substances having a high safety. The above production process is characterized by involving the step of immersing beer-cake obtained in the process of the production of beer in an organic polar solvent; the step of separating the extract from the immersion solution; and the step of concentrating the extract. The above barely malt oil is obtained by immersing beer cake obtained in the process of production of beer in an organic polar solvent; separating the extract from the immersion solution; and then concentrating the extract. See abstract. All of the claim limitations are disclosed in the prior art. Therefore, these claims are anticipated.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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7. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over NOF CORP (JP 11-113530).

Applicants claim a functional food comprising a sphingoglycolipid derived from a tuberous and corm vegetable or oil cake. Applicants disclose it is known in the art that ceramides composed of sphingosine and fatty acids.

NOF CORP discloses a health food capable of being orally administered to exhibit beauty effects such as a skin-moisturizing effect, a skin-protecting effect, a skin roughness-preventing effect, and a skin wrinkle-preventing effect by including ceramide as an active agent. The health food is obtained by adding 0.001-2 wt.%, preferably 0.01-1 wt. % of ceramide to a food. The ceramide extracted from bovine brain, wheat, rice soybeans, spinach, yeast or the like. The ceramide is administered at a daily dose of 1-1000 mg preferably 5 to 100 mg. The health food is produced in the form of tables, capsules, powders, liquids, and may be added to confections, breads or drinks. NOF CORP does not disclose the sphingoglycolipid to be derived from a tuberous and corm vegetable or oil cake.

It is the position of the examiner the prior art reads on the product, a food comprising a sphingoglycolipid. Even though product-by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. Therefore, the instant product is obvious in view of the prior art.

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8. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Q.P. CORPORATION.

Applicants claim a cosmetic comprising a sphingoglycolipid derived from a tuberous and corm vegetable or oil cake. Applicants disclose it is known in the art that ceramides composed of sphingosine and fatty acids.

Q.P. CORPORATION disclose phytoceramide, as a base material, is extracted and refined from rice containing sphingoglycolipids (cerbroside) in high purity and meets the specification for "Rice Bran Sphingoglycolipid" in JCIC (Japanese Cosmetics Ingredients Codex) and the INCI name is "Glycosphingolipids". COSMESOME CM-1 can be widely used as a cosmetic ingredient providing the skin with emollient effect and preventing rough skin. Q. P. CORPORATION does not disclose the sphingoglycolipid to be derived from a tuberous and corm vegetable or oil cake.

It is the position of the examiner the prior art reads on the product, a cosmetic comprising a sphingoglycolipid. Even though product-by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. Therefore, the instant product is obvious in view of the prior art.

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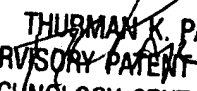
*Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel M. Bennett whose telephone number is (703) 308-8779. The examiner can normally be reached on Monday through Friday, 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

R. Bennett  
June 11, 2003

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600